

K071517

APR - 2 2008

5. 510 (k) SUMMARY (as required by 807.92 (c))

807.92 (a)(1)

Submitted by:

**A.b.m. Italia S.p.A., Via Ing. G. Taliercio, 1,
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FEBRUARY, 28th 2008

807.92 (a)(2)

Trade name:

- PBS 0,6 lt.
- PBS 0,6 lt. with narrow base
- PBS 0,8 lt.
- PBS 1,5 lt.
- PBS 2 lt.
- PBS 5 lt.
- PBS 7 lt.
- PBS 12 lt.
- CS 2 lt.
- CS 3 lt.
- CS 4 lt.
- CS 5 lt. Low
- CS 5 lt. High
- CS 6 lt.
- Nursy 3 lt.
- Nursy 5 lt.
- Nursy 10 lt.

Common name: Sharps container

Classification name: Sharps container 80 MMK 880.5570



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807.92 (a)(3)

Equivalent device being legally marketed:

For PBS Line:

Trade name:

Sharps-Tainer

Manufactured by: **WINFIELD INDUSTRIES**

510K approval Number: **K961878**

For CS and Nursy Line:

Trade name:

The sharps collection and disposal system

Manufactured by: **DEVON INDUSTRIES, INC.**

510K approval Number: **K9451197**

807.92 (a)(4)

Description:

Our sharps containers are made of Polypropylene resin and coloured using Masterbatch which contains no heavy metals or cadmium.

These materials allow us to produce a very safe, high quality puncture resistant container.

Each container is comprised of a Body (either square or round) and a lid. The lids are a very safe and secure fit.

All containers are vertical entry.

All containers have the maximum filling level line as well as required labelling in accordance with current legislation.

CONTAINER (code)	SIZE (LT)	SHAPE	FEATURES
PBS 0.6	0.6	ROUND	Closing by pressing the small lid
PBS 0.6 S (with narrow base)	0.6	ROUND	Closing by pressing the small lid
PBS 0.8	0.8	ROUND	Closing by pressing the small lid
PBS 1.5	1.5	ROUND	Closing by pressing the small lid
PBS 2	2	ROUND	Closing by pressing the small lid
PBS 5	5	ROUND	Closing by pressing the small lid
PBS 7	7	ROUND	Closing by pressing the small lid
PBS 12	12	ROUND	Closing by pressing the small lid
CS 2	2	SQUARE	Closing by turning the round part
CS 3	3	SQUARE	Closing by turning the round part
CS 4	4	SQUARE	Closing by turning the round part
CS 5 H	5	SQUARE	Closing by turning the round part
CS 5 L	5	SQUARE	Closing by turning the round part
CS 6 H	6	SQUARE	Closing by turning the round part
NURSY 3	3	SQUARE	Closing by inserting the round lid
NURSY 5	5	SQUARE	Closing by inserting the round lid
NURSY 10	10	SQUARE	Closing by inserting the round lid



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These containers are equipped with a permanent closure system, that is the final method of closure. Once the container is closed permanently it is locked closed. It can not manually re-open. This is a very safe method of preventing injury.

Once the container is full it is locked and then disposed of. It is safe for anyone coming into contact with the container.

807.92 (a)(5)

Intended use:

These containers are intended for use by healthcare providers such as hospitals, laboratories, medical clinics, veterinary clinics and other facilities. The containers are designed and used for the safe collection and disposal of sharps such as needles, scalpels, lancets and other sharp instruments.

They were designed in collaboration with the people from infectious control from different countries in order to satisfy in the best way the hospital's needs as well as the highest security standards.

Furthermore, three different lines offers to our customers and end users to choose the lid closure and design which they prefer:

PBS line – round shape container with a very simple definitive closure

CS line – square shape container with turning lid for definitive closure

Nursy line – square shape container with a high shock resistance

All our containers once full must be disposed.

807.92 (a)(6)

All containers of PBS Line are substantially equivalent to **Sharps-Tainer** container as follows:

Comparison table

	PBS Line	Sharps-Tainer
Target population	Healthcare professional	Healthcare professional
Indication for use	Healthcare sharps	Healthcare sharps
Where used	Healthcare facilities/labs	Healthcare facilities/labs
Performance	Single use	Single use
Construction	Injection moulding	Injection moulding
Materials	Polypropylene	Polypropylene
Lid	Closure by pressing the lid	Closure by pressing the lid
Opening	Rounded opening	Squared opening
Needle elimination	By vertical dropping	By vertical dropping

All containers of CS and Nursy Line are substantially equivalent to **The sharps collection and disposal system** container as follows:



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Comparison table

	CS and Nursy Line	The sharps collection and disposal system
Target population	Healthcare professional	Healthcare professional
Indication for use	Healthcare sharps	Healthcare sharps
Where used	Healthcare facilities/labs	Healthcare facilities/labs
Performance	Single use	Single use
Construction	Injection moulding	Injection moulding
Materials	Polypropylene	Polypropylene
Lid	CS: Closure by rotation of the lid Nursy: Closure by rotation and pressure of lid	Closure by rotation of the lid
Opening	Rounded opening	Rounded opening
Needle elimination	By vertical dropping	By vertical dropping

807.92 (b)(1-2-3)

Clinical tests: not applicable.

Non clinical tests: The summary data derived from mechanical tests are as follows:

	PREDICATE DEVICE: Sharps-Tainer	AP MEDICAL PBS	PREDICATE DEVICE: The sharps collection and disposal system	AP MEDICAL CS - NURSY
1. Impact Resistance	Pass	No damage after dropping from 1 mt	Pass	No damage after dropping from 1 mt
2. Puncture Resistance (base, sides, closure, top)	Pass	Average > 18 N, min >12.5 N	Pass	Average > 18 N, min >12.5 N
3. Leak Resistance (sides and bottom)	Pass	The containers are leak proof on sides and bottom	Pass	The containers are leak proof on sides and bottom Nursy line is leak proof also on the top

Conclusions:

The containers, as tested, satisfy the criteria as the predicate devices, and are capable of preventing the loss or dispersal of the contents for conditions normal to transport.



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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
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APR - 2 2008

Mr. Franco Grava
Product Manager
A.B.M. Italia S.P.A
Via Lng. G. Taliercio, 1
Roncadelle Di Ormelle,
Italy 31024

Re: K071517

Trade/Device Name: AP medical sharps containers 0.6 – 12 Lt. (PBS 0.6 lt., PBS 0.6 lt. with narrow base, PBS 0.8 lt., PBS 1.5 lt., PBS 2 lt., PBS 5 lt., PBS 7 lt., PBS 12 lt., CS 2 lt., CS 3 lt., CS 4 lt., CS 5 lt. Low, CS 5 lt. High, CS 6 lt., Nursy 3 lt., Nursy 5 and Nursy 10 lt.)

Regulation Number: 880.5570

Regulation Name: Hypodermic Single Lumen Needle

Regulatory Class: II

Product Code: MMK

Dated: February 28, 2008

Received: March 5, 2008

Dear Mr. Grava:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

INDICATION FOR USE

510 (K) Number: K071517

Device name: AP medical sharps containers 0,6 – 12 Lt:

(PBS 0,6 lt., PBS 0,6 lt. with narrow base, PBS 0,8 lt., PBS 1,5 lt., PBS 2 lt., PBS 5 lt., PBS 7 lt., PBS 12 lt., CS 2 lt., CS 3 lt., CS 4 lt., CS 5 lt. Low, CS 5 lt. High, CS 6 lt., Nursy 3 lt., Nursy 5 , Nursy 10 lt.)

Applicant: A.b.m. Italia S.p.A., Via Ing. G. Taliercio, 1, 31024 Roncadelle di Ormelle (TV), ITALY

Indications for Use:

AP Medical sharps containers are intended for use by healthcare providers such as hospitals, laboratories, medical clinics, veterinary clinics and other facilities for safe disposal of sharps such as Needles, Scalpels, Lancets and other Sharp Instruments.

Three different lines are offered to our customers and end users:

PBS line – disposable round containers with access inlets on the lid, for sharps disposal

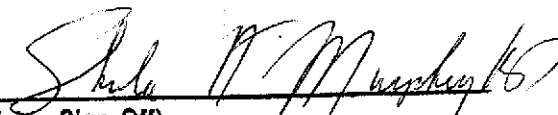
CS line – disposable square containers with rotating lid for sharps disposal

NURSY line – disposable square containers with hermetic permanent closure for sharps disposal

Prescription Use _____
(21 CFR 801. Subpart D)

and/or Over-the-Counter Use ☒
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device


(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K071517